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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,120	09/25/2001	Marvin L. Schilling	BWS-00-07	9970

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BERND W. SANDT  
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EXAMINER:

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/964,120

Applicant(s)

SCHILLING ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt of Appeal Brief filed on May 12, 2004 is acknowledged. Claims 42-51 are pending in this application. Claims 1-41 stand cancelled.

#### ***Status of Application***

In view of the Appeal Brief filed on May 12, 2004, PROSECUTION IS HEREBY REOPENED. The new rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of US patent 4,250,139 to Luck et al in further view of US patent 4,404,033 to Steffan et al.**

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Moore teaches the obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing 5.15% sodium hypochlorite and water to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in 3% hydrogen peroxide to sterilize the cartilage without denaturing the collagen. The product is diced. (Note example 1). The product of example 1 is dried at an average temperature of 110 Fahrenheit to remove over half the water content in example 12. These samples have the advantage of improved shelf life, reduced volume, and better handling.

Moore does not teach adding salt or instant amount of salt.

Luck et al teach a microwave sterilization of dry protein that retains the chemical, physical, and physiological properties of the proteinaceous materials. See abstract. Luck teaches a wide variety of proteinaceous material such as instant collagen. Further, the proteins are obtained from sources such as skin, bone, tendons, and cartilage. See column 2, lines 10-20. Luck stresses the importance of ensuring that the protein is unchanged so it retains its activity. See column 2, lines 20-26. Luck et al teach the protein is substantially dehydrated by placing the protein material in an aqueous solution in combination with salt, which is adventitiously present in the medium. The water is then removed by lyophilization. This drying may be done by freeze-drying, vacuum drying or drying agents to substantially remove the water and preferably to remove all the water. See column 2, lines 31-50. The lyophilization temperature taught is below 75 degrees Celsius (167 degrees Fahrenheit) and preferably below 45 degrees Celsius (113 degrees Fahrenheit). The examples utilize temperatures of 30 or 40 degrees Celsius. See column 3, line 54 and column 4, lines 57.

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Steffan teaches the method of making collagen fibers for surgical use. Steffan teaches the use of sodium chloride in the amount of 5 to 15% for dehydration purposes

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Moore and Luck et al and additionally utilize salt for dehydrating the cartilage. One would be motivated to do so since Luck et al teach a method dehydrating protein material by placing the material in an aqueous medium containing salt, followed by lyophilization at instant temperatures to remove all the water from the protein material and yet retain the physiological activity of the protein. Therefore, one would be motivated to further add salt to Moore's method of dehydration to provide for an additive effect of further facilitating and hastening the dehydration process. Moreover, it is prima facie obvious to combine two dehydrating techniques taught by the prior art for the same purpose, i.e. drying material containing protein and simultaneously retaining the activity of the material, in order to form a third process for the very same purpose.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to Steffan and utilize the instant amount of salt in Moore's dehydration method. One would be motivated to do so since Steffan teaches various salts are utilized to dehydrate collagen fibers, which is optimally utilized at the instant amount. Furthermore, the application of salt in the dehydration of collagen specifically versus cartilage containing collagen would still yield the same result since the function of salt as the drying agent will remain the same.

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It is the examiner's position that since the prior teaches the utilization of instant amount of salt, this will implicitly yield a product with the recited limitation of "at least 45%" salt content in the dried material.

**Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of US patent 4,250,139 to Luck et al in view of US patent 4,404,033 to Steffan et al, in further view of JP 59-088065.**

As set forth above, Moore teaches dehydrating cartilage by soaking in an aqueous antimicrobial solution, followed by heating the cartilage to reduce moisture content. Luck et al and Steffan teach the use of salt in dehydrating methods.

The references do not teach the use of lecithin or cellulose.

JP teaches dehydration of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not degrade the protein. See page 2 of translated document. The powder is then hot air dried. The lecithin is utilized to enable easy washing of the product to remove extraneous material and provide for a uniform solution. See page 2-3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of references and utilize lecithin in the process. One would be motivated to do so since JP teaches lecithin enables easy washing of the animal product and provides for a uniform solution prior to dehydration by the application of heat. One would expect similar results since all the references are in the same field of endeavor, i.e. the process of dehydrating animal products while maintaining the activity of the protein.

**Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,645,851 to Moore in view of JP 59025637.**

Moore teaches the obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing 5.15% sodium hypochlorite and water to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in hydrogen peroxide to sterilize the cartilage without denaturing the protein. The product is diced. (Note example 1). The product of example 1 can be dried at an average temperature of 110 Fahrenheit to remove over half the water content (example 12). These samples have the advantage of improved shelf life, reduced volume, and better handling.

Moore does not specify the water content. Additionally, Moore does not teach adding salt.

JP teaches treating scallop by dehydrating using salt. JP teaches using 7-15% salt to dehydrate the ligaments of scallops. Note ligaments inherently contain collagen I. Note translation, see first process of page.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Moore and JP and additionally utilize salt for dehydrating the cartilage. One would be motivated to do so since JP teaches the method of dehydrating ligaments with salt. Therefore, one would be motivated to further add salt to Moore's method of dehydration to provide for an additive effect of further facilitating and hastening the dehydration process. Moreover, it is prima facie obvious to combine two dehydrating techniques taught by the prior art for the same purpose, i.e. drying material containing protein and simultaneously retaining the activity of the material, in order to form a third process for the very same purpose.

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Further, one would expect similar results of utilizing salt to dehydrate Moore's cartilage since JP dehydrates ligaments, which contains collagen albeit a different type of collagen than the one instantly claimed. The application of salt in the dehydration of Type I collagen versus Type II does not change the primary function of salt as a dehydrating agent. Salt will nonetheless act in a similar manner of removing water from the material to be dehydrated.

Lastly, it is the examiner's position that since the prior teaches the utilization of instant amount of salt, this will implicitly yield a product with the recited limitation of "at least 45%" salt content in the dried material.

**Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of JP 59025637 in further view of JP 59-088065.**

As set forth above, Moore teaches dehydrating cartilage by soaking in an aqueous antimicrobial solution, followed by heating the cartilage to reduce moisture content. JP teaches the utilization of salt to further dehydrate animal products.

The references do not teach the use of lecithin or cellulose.

JP teaches dehydration of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not degrade the protein. See page 2 of translated document. The powder is then hot air dried. The lecithin is utilized to enable easy washing of the product and provide for a uniform solution. See page 2-3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Moore, JP 59025637, and JP 59-088065 and utilize lecithin in the process. One would be motivated to do so since JP teaches lecithin enables easy



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washing of the animal products and provides for a uniform solution prior to dehydration. One would expect similar results since all the references are in the same field of endeavor, i.e. the process of dehydrating animal products while maintaining the activity of the protein.

**Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 288405 (abstract) in view of US patent 5,562,535 to Puppolo.**

EP '405 teaches a process for providing meat-containing protein. The process involves heating meat, which includes muscle, cartilage, bone, and fat in an aqueous medium for 80 to 130 degrees Celsius for 8 to 20 hours. The mixture is cooled, followed by removing the fat, and concentrating the aqueous phase by evaporation. The aqueous medium contains sodium chloride in the amount of 0.1 to 4% based on the weight of the meat. See abstract.

EP '405 does not disclose the instant temperature of 110 Fahrenheit.

Puppolo teaches a method of producing dehydrated shark cartilage without denaturing the proteins. The reference teaches that prior art methods of dehydrating such as convection ovens, vacuum ovens, and freeze drying techniques use temperatures that are high enough to cause the loss of proteins (column 1, lines 5-16). After the undesirable components are removed from the cartilage, the removal of all water and solvent is accomplished by drying the product in a sonic chamber at 85 degrees Fahrenheit or lower (col. 2, lines 34-45). This temperature does not denature the proteins and removes all the solvent and water. See column 2, lines 34-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of EP '405 and Puppolo and utilize the instant temperature. One would motivated to so since Puppolo discloses that 85 Fahrenheit not only sufficiently dehydrates the animal product by removing all the water or solvent, dehydrating at that

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temperature does not denature the proteins contained in the animal material. Therefore, one would be motivated to utilize low temperatures to retain the activity of the protein contained in the animal material.

**Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 288405 in view of US patent 5,562,535 to Puppolo, in further view of JP 59-088065.**

As set forth above, EP teaches the process of providing dehydrated meat and Puppolo teaches the instant temperatures.

The references do not teach the use of lecithin or cellulose.

JP teaches dehydration of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not degrade the protein. See page 2 of translated document. The powder is then hot air dried. The lecithin is utilized to enable easy washing of the product and provide for a uniform solution. See page 2-3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references cited above and utilize lecithin in the process. One would be motivated to do so since JP teaches lecithin enables easy washing of the animal products and provides for a uniform solution prior to dehydration. One would expect similar results since all the references are in the same field of endeavor, i.e. the process of dehydrating animal products while maintaining the activity of the protein.

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*Conclusion*

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
Examiner  
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